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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/523,767 | 03/11/2000 | Eugene de Juan JR. | 49.603 (1699) | 5862 |
| 21874 | 7590 | 06/02/2005 | EXAMINER | |
| EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205 | | | BAXTER, JESSICA R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3731 | |

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/523,767

Applicant(s)

DE JUAN ET AL.

Examiner

Jessica R. Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 55, 63-65 and 67-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 55, 63-65 and 67-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 07272004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2, 4, 80, 81, 82, 83, 84, 85, 86, 87 and 88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 depends from claim 80 and claim 80 depends from claim 2. It is unclear what the proper claim dependency should be.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1- 12, 14, 22, 55, 63, and 67-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,487,725 to Peyman in view of U.S. Patent No. 3,618,594 to Banko.

Peyman discloses a surgical procedure that does not utilize the use of entry alignment devices. Peyman discloses that either an incision is made or the device is adapted to pierce the eyeball without requiring a prior incision (Column 9 lines 30-37). Banko teaches the claimed invention except for the size necessary to ensure a self-sealing entry aperture.

Peyman teaches that the devices used in his procedure are small enough to allow the wound to be self-sealing (Column 4 line 65-67). It would have been obvious to one having ordinary

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skill in the art at the time the invention was made to size the entry alignment device of Banko small enough to be self-sealing in order to avoid the use of sutures. In addition, Banko teaches that entry alignment devices are used in surgical procedures to provide stability and a supporting point for the surgeon's hand (Column 7 lines 14-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Peyman '725 with the device of Banko in an appropriate size to prevent the requirement of sutures in order to provide stability and support for the surgeon performing the procedure on the eye.

Peyman teaches that the devices used in his procedure are small enough to allow the wound to be self-sealing (Column 4 line 65-67). Peyman discloses that a surgical instrument used in the procedure is less than 25 gauge and may be an infusion cannula or an vitreous cutter or aspirator (Column 2 lines 7-19 and Column 5 lines 15-17). Banko discloses that the entry alignment device is in the form of a metal cannula. Peyman discloses that a plurality of entry alignment devices may be inserted into the eye (FIG. 11). Peyman discloses that the device is inserted at an angle with respect to a normal to the eye (FIG. 5). The normal to the eye can be any line that is perpendicular to the eye. Peyman discloses that the infusion cannula may be inserted directly through the sclera and conjunctiva or through the entry alignment device (Column 4 lines 36-62).

5. Claims 13, 15-21, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman '725 in view of Banko '594, further in view of U.S. Patent No. 5,919,158 to Saperstein et al.

Peyman discloses the claimed invention except for the insertion of a light source. Saperstein teaches the use of a light source to illuminate an area the surgeon is working on (see Column 5 lines 13-15). Therefore, it would have been obvious to one having ordinary

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skill in the art at the time the invention was made to insert a light source in order to illuminate the area in which the surgeon is working.

Peyman discloses inserting a high-speed vitreous cutting/aspirating instrument and removing vitreous gel using the high-speed vitreous cutting instrument and implementing a corrective procedure for the retina (see Column 4 line 63 – Column 5 line 18). Banko discloses that the entry alignment device is in the form of a metal cannula. Peyman discloses that a surgical instrument used in the procedure is less than 25 gauge and may be an infusion cannula (Column 4 lines 38-46). Peyman discloses that the step of inserting includes inserting the instruments, hence the entry alignment device, at an angle less than 45 degrees with respect to a normal to the eye. Peyman discloses that the infusion cannula may be inserted directly through the sclera and conjunctiva or through the entry alignment device (Column 4 lines 27-46).

Response to Arguments

6. Applicant's arguments filed March 7, 2005 have been fully considered but they are not persuasive.
7. Applicant argues that the prior art references pull back the conjunctiva. Applicant has only pointed out that incisions are made in the sclera (Peyman '725). These incisions are optional and can be made by the device as it is inserted (Column 9 lines 29-36). It appears known in the art to use devices to puncture the eye with the device without requiring a sclerotomy. Applicant also argues that the prior art requires the conjunctiva to be pulled back before any incision is made into the sclera. However, applicant has not clearly pointed out that this is the case in the cited references.

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Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R. Baxter whose telephone number is 571-272-4691. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


jrb

Jessica R Baxter
Examiner
Art Unit 3731


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
5/31/05.